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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,383	03/04/2002	Maria Laura Gennaro	20869-8	7070
28221 7590 02/04/2009 PATENT DOCKET ADMINISTRATOR LOWENSTEIN SANDLER PC 65 LIVINGSTON AVENUE			EXAMINER	
			SWARTZ, RODNEY P	
ROSELAND, N	<del>-</del>		ART UNIT	PAPER NUMBER
			1645	
			MAIL DATE	DELIVERY MODE
			02/04/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Application/Control Number: 10/009,383 Page 2

Art Unit: 1645

## **DETAILED ACTION**

1. Applicant's Response to Final Office Action, received 16 December 2008, is acknowledged. Claims 3, 4 and 7 have been amended.

2. Claims 3-7, 9 and 10 are pending and under consideration.

## **Rejections Maintained**

3. The rejection of claims 3-7, 9 and 10 under 35 U.S.C. 103(a) as being unpatentable over Reed et al (WO98/16645, 23 April 1998), is maintained.

Applicant argues that Reed et al would not motivate one of skill in the art to create a vector, cell, or composition, comprising a DNA molecule or sequence encoding MBTN4 polypeptide (SEQ ID NO:110) and at least one additional DNA sequence encoding a polypeptide which is encoded by *M. tuberculosis* but is not encoded by the genome of BCG strain of *M. bovis*. Applicant cites page 21, lines 24-27 of Reed et al "embodiments in which more than one polypeptide is employed, the polypeptides used are preferably complementary" as evidence that Reed et al polypeptides would have different characteristics in order to be complementary to each other. The instant polypeptides share similar characteristics.

The examiner has considered applicant's arguments, but does not find them persuasive. It is noted that the claims are directed to MTBN4, not MBTN4. The cited instance in Reed et al is merely a "preferred" embodiment and does not exclude other embodiments. Thus, the teachings of Reed et al would have suggested one of ordinary skill in the art to place the sequence into a vector, transform a host cell with that vector, and to admix said vector with a pharmaceutically acceptable diluent or filler as taught by Reed et al for the other DNA sequences in the document (page 39, line 18 to page 45, line 1; claims 5-8, 40-47).

## Conclusion

Application/Control Number: 10/009,383 Page 3

Art Unit: 1645

4. No claims are allowed.

5. Any inquiry concerning this communication or earlier communications from the Examiner

should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571)

272-0865. The examiner can normally be reached on Monday through Wednesday from 9:00

AM to 7:30 PM EST. Thursday is the examiner's work at home day.

If attempts to reach the Examiner by telephone are unsuccessful, please contact the

Examiner's Supervisor, Robert B. Mondesi (571)272-0956.

The fax phone number for the organization where this application or proceeding is

assigned is (571) 273-8300.

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PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Rodney P. Swartz, Ph.D./

Primary Examiner, Art Unit 1645

January 27, 2009